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510(k) Summary

Flowtron Foot Garments – Sterile

DEC 7 2012

Name & Address:	ArjoHuntleigh AB Verkstadsvägen 5 241 38 Eslöv, SWEDEN
Telephone:	+(44) 29 2044 7084
Fax:	+(44) 29 2049 2520
Prepared:	6 December 2012
Contact:	David Moynham – Regulatory Affairs Engineer
Device Name:	Flowtron Foot Garments - Sterile
Common Name	Sleeve, Limb, Compressible

Classification	Class	Product Code	Classification Regulation
	II	JOW	21 CFR 870.5800

Classification Name: Sleeve, Limb, Compressible

Predicate Device: K965153, Huntleigh FP5000 System, Model FP5000

Indications for Use:

- Prevention of Deep Vein Thrombosis (DVT)
- Enhancement of venous & arterial circulation
- Prevention of venous stasis
- Assist healing of cutaneous ulcers
- Reduction of acute or chronic edema
- Reduction of lower limb pain due to surgery or trauma
- Reduction of compartmental pressures

Description :

The Flowtron Foot Garment is a wrap around foot garment comprising of a bladder and surrounding material intended to apply cyclic compression to the foot to improve return venous blood flow to prevent and reduce the risk of Deep Vein Thrombosis (DVT).

The Flowtron Foot Garment is connected to an ArjoHuntleigh Flowtron pneumatic pump. The pump controls and generated the delivery of air to inflate and deflate the Foot Garment in a cyclic manner.

Flowtron Foot Garments are configured with a custom design connector that means that they are only compatible with ArjoHuntleigh Flowtron pneumatic pumps .

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Models

Model REF	Device	Feature
FG100S	Flowtron Foot Garment Regular - FG100S	Sterile
FG200S	Flowtron Foot Garment Large- FG200S	Sterile

Substantial Equivalence: The Flowtron Foot Garments – Sterile and the Foot Garments included in the predicate device clearance are identical in all respects including materials, construction, performance and indications for use. The only difference being the sterility of the Flowtron Foot Garments.

Full details of the validation of sterility processing and shelf life stability have been submitted for sterile garments.

Technologies Summary: The Flowtron Foot Garments – Sterile and the Foot Garments included as part of the predicate device clearance are identical in all respects including materials, construction, performance and indications for use. The only difference in technology being the sterility aspect. Sterile garments being processed using Ethylene Oxide in accordance with ISO 11135.

Conclusion: The Flowtron Foot Garments – Sterile and the Foot Garments of the predicate device are substantially equivalent. Issues raised by the sterilisation process have been addressed in the validation process and these demonstrate that the sterile Foot Garments remain safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 7 2012

Arjohuntleigh
C/O Mr. David Moynham
35 Portmanmoor Road
Cardiff, S. Glamorgan, CF24 5HN, United Kingdom

Re: K122330
Trade/Device Name: Flowtron Foot Garment - Regular – Sterile, FG 100S and Flowtron Foot Garment – Large- Sterile, FG 200S
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 2, 2012
Received: November 7, 2012

Dear Mr. Moynham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh

for

Bram D. Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number: K122330

Device Name: **Flowtron Foot Garments-Sterile**

Indications for Use:

- Prevention of Deep Vein Thrombosis (DVT)
- Enhancement of venous & arterial circulation
- Prevention of venous stasis
- Assist healing of cutaneous ulcers
- Reduction of acute or chronic edema
- Reduction of lower limb pain due to surgery or trauma
- Reduction of compartmental pressures

Prescription Use		Over-The-Counter Use
YES	AND/OR	**NO**
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122330